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**From:** "Martha M. Rumore" <mrumore@frierlevitt.com>  
**Sent:** Tue 12/8/2020 5:55:00 PM (UTC)  
**To:** Charles Boyd <CharlesB@Safechain.com>  
**Cc:** Abbie Divilio <AbbieD@Safechain.com>  
**Subject:** FW: Safe Chain Response to Gilead Letter of Nov 23  
**Attachment:** Gilead Letter Final.pdf

Hi:

For your records.  
My Best,  
Martha

Martha M. Rumore, PharmD, MS, JD, LLM  
*Senior Counsel*

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**From:** Martha M. Rumore  
**Sent:** Monday, December 7, 2020 4:46 PM  
**To:** peter.colosi@gilead.com  
**Subject:** Safe Chain Response to Gilead Letter of Nov 23

Dear Mr. Colosi:

GOVERNMENT  
EXHIBIT

208

1:24-cr-20255-WPD

GX 208.001

DOJ-PPM-0000115703

Please see Safe Chain Solution's response to your November 23, 2020 letter.

Please let me know if you have any additional questions.

Very truly yours,

Martha M. Rumore, PharmD, MS, JD, LLM  
*Senior Counsel*

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Martha M. Rumore, Pharm.D., Esq.  
direct: 646.970.3226  
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December 7, 2020

VIA EMAIL: Peter.colosi@gilead.com

Peter M. Colosi  
Senior Counsel, Anti-Counterfeiting  
Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404

RE: Your November 23, 2020 Letter to Safe Chain Solutions, LLC

Dear Mr. Colosi:

We represent Safe Chain Solutions, LLC and are in receipt of your letter of November 23, 2020 to their Legal Department.. You requested a response no later than December 7, 2020. This correspondence serves as that response.

Your letter states two reasons for writing to Safe Chain Solutions: (1) to follow up on correspondence regarding BIKTARVY® (Lot CDGXKA) and (2) to seek cooperation with your investigation into BIKTARVY® (Lot CCXKVA). As an initial matter, Safe Chain is committed to fully cooperating with your investigation. We proactively take action to prevent the distribution and sale of counterfeit products, including working with Federal and Local authorities to enforce laws.

Regarding (1) BIKTARVY® (Lot CDGXKA), Safe Chain contacted your QC Complaints office on October 5, 2020 attempting to verify T3 information which was provided to you together with a photo of the product bottle. The T3 information indicated you sold 5 bottles of that lot number to Rochester Drug Co-op, Inc. in Fairfield, NJ. The matter was assigned PR-200633. It is important to point out that Safe Chain proactively contacted Gilead requesting T3 information verification.

Via email on November 9, 2020, more than a full month later, your office made a determination that the product was illegitimate. Your email stated "The information contained in the pedigree/transaction history is inconsistent with our records." You then indicated you determined the product as illegitimate. As you know, once Gilead, the manufacturer, made that determination on the basis of T3 information, the manufacturer has a duty to report this to the Food and Drug Administration (FDA) on Form 3911 within 24 hours of that

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determination. As a wholesaler, we immediately quarantined the product and awaited further results of your investigation and/or recall instructions from your office which were not forthcoming. We had additional bottles of this lot which we placed in quarantine and have not yet returned. Due to the cost of the medication, we were going to return to our vendor for other product (not this lot). While we understand the financial implications to Gilead that a product recall may trigger, FDA notification was your responsibility inasmuch as your investigation revealed the product was illegitimate and details of that investigation were only known to you and not shared with Safe Chain. At this juncture we are requesting you provide us with a copy of any documentation you submitted to the FDA for our records. Additionally, we respectfully request to know if Gilead has received any inquiries similar to PR-200633, detected any similar problems or reports involving your third-party manufacturers, or has conducted any recalls to the Wholesale or Retail Level of BIKTARVY® bearing Lot # CDGXKA.

Regarding (2) BIKTARVY® (Lot CCXKVA), your November 23<sup>rd</sup> letter is the first time we are being contacted that there is an investigation into this Lot number. Your letter indicated you have identified the bottle in question contained foreign tablets instead of BIKTARVY® and that Safe Chain Solutions, Inc. may be a possible source. Although you have not indicated that particular bottle of that particular lot came from Safe Chain, or another wholesaler, as a precautionary measure and with our full cooperation, we have quarantined the particular lot in question and can assure you we are purchasing from an authorized trading partner. Additionally, we confirm the invoice you have received from White Cross Pharmacy which was attached to your November 23<sup>rd</sup> letter. Please advise us upon making a determination of the wholesaler involved. Additionally, please provide any recall notification once you make that determination with FDA.

I am available to discuss this matter further should you require clarification. Please provide the requested information and response no later than December 11, 2020.

Respectfully,

**FRIER LEVITT, LLC**

*/s/ Martha M. Rumore*

Martha M. Rumore, PharmD, Esq

cc: Safe Chain Solutions, Inc. (via email)